March 7, 2009

President Barack Obama
White House
1600 Pennsylvania Ave NW
Washington, DC 20500

Re: Health Care Reform
Medical corruption involving federal health agencies and medical societies.

Dear President Obama,

I am writing to tell you of certain practices of the medical trade that are used for health care denials so that HMO's and other health insurers can minimize their costs and increase their profitability. One outcome of this method of patient abandonment is that the patients can be debilitated to the extent that they become wards of the government. This results in increased welfare and assistance costs for state and federal governments resulting from the dereliction of medical responsibilities by insurers. This is wrong and something that the nation doesn't need right now.

I will try to keep this as brief and simple as I can. It is a complex topic. If there is a need for more information, I can provide it.

"Evidence-based medicine" as a foundation for health care denials

A core tool for the manipulation of medical standards is the use of "evidence-based medicine." This can involve such tactics basing recommendations on highly selective and exclusionary references as well as using disease definitions that are so restrictive, few can meet the definition. Evidence-based medicine results in clinical practice guidelines. The authors of these guidelines can have massive conflicts of interest including, for example, arrangements with pharmaceutical companies, interests in test kits and vaccines, and financial relationships with HMO's and other health insurers.

In fact, evidence-based medicine is not necessarily based on medicine. Most recommendations are based on the opinions of the authors and influenced by the conflicts mentioned above and other conflicts of interest.

These clinical practice guidelines can become clinical practice "rules" or mandates resulting in physicians being denied the freedom to treat in the best interests of the patient. Physicians who do not conform to guidelines can be reprimanded in one form or another including complaints to medical boards and possible loss of license to practice.

The case of Lyme disease.

I am most familiar with Lyme disease so I will cite some specifics relating to this example. Lyme disease may well be the most corrupted of any medical condition.

Lyme disease clinical practice guidelines have been issued by the Infectious Diseases Society of America (IDSA) and, more recently, by the International Lyme and Associated Diseases Society (ILADS). My focus will be on the IDSA guidelines since this is the basis for Lyme denials used by HMO's and insurers (http://www.journals.uchicago.edu/doi/full/10.1086/508667).

IDSA issues many clinical practice guidelines and I would like to make it clear that I do not consider all of IDSA's guidelines to be corrupted.

IDSA's most recent Lyme disease guidelines (2006) are under review because of an investigation by Connecticut's Attorney General (http://www.ct.gov/ag/cwp/view.asp?a=2795&q=414284).

The latest version of the IDSA guidelines covers some coinfections of Lyme disease as well. There were 14 authors of the guidelines, 11 of these authors promoted as "experts" on Lyme disease. The substantial conflicts of interest of most of these authors were not revealed in the disclosure section of the guidelines. These undisclosed conflicts included interests in private companies, payments by pharmaceutical companies and HMO's and health insurers, payments for research, and financial interests in Lyme disease testing and vaccines. Of course, the lawsuits and very large number of complaints against some of the authors relating to medical malpractice and damage from Lyme vaccines also was not mentioned. While disclosure, per se, does not solve the problems of conflicts of interest, it would at least provide some transparency. The fundamental problem is that conflicts of interest can influence recommendations which, in turn, can take on the force of law.

The IDSA authors claim that a comprehensive review of medical literature was undertaken and that 405 references were used for Lyme disease. In fact, only 337 of these references relate to Lyme disease. Of these, over 50% were written by the authors themselves. Most of the recommendations were based on no more than the "expert opinion" of the panel.

At the time of the drafting of the guidelines, there were over 7,000 citations to Lyme disease in the National Libraries of Medicine. Studies that contradicted the opinion of the authors were eliminated.

A CDC employee with patent interests in Lyme disease, Barbara J. Johnson, is credited as having been a consultant in the formulation of the IDSA guidelines.

Trivialization and misinformation about Lyme disease

One net effect of the IDSA guidelines is to characterize Lyme disease in a manner that makes diagnosis more restrictive and, therefore, minimize the apparent prevalence of the disease. Another more important impact is to severely limit treatment. IDSA claims that a few weeks of antibiotics completely cures any stage of the disease and that any ongoing symptoms after treatment are not due to Lyme disease. This has been completely discredited in both foreign and domestic research and by the clinical experiences of doctors who treat Lyme disease with long-term antibiotics. Kaiser Permanente is a prime example of an HMO that adheres exclusively to the IDSA guidelines. Doctors who do not conform are reprimanded. This also applies to Permanente doctors who try to help patients by cooperating with treatment plans ordered by an independent Lyme specialist, who the patient sees at their expense.

Lyme disease can be expensive to treat and many have become destitute and homeless because of medical expenses and inability to work. Through welfare payments and other assistance, they then become dependent on the government for support. The IDSA guidelines enable HMO's and health insurers to escape expense and liability and transfer costs to the government. Moreover, the panelists themselves can escape culpability since many do not have a clinical practice subject to malpractice and, in the event that they do, they can refer to their "guidelines" as a "standard of care" and use their cohorts as "expert witnesses".

The disease is also trivialized by IDSA and many related symptoms, such as serious cardiac outcomes, have been excluded in the guidelines. Complications of improperly treated Lyme disease can and do cause death and permanent disability.

The conflicts of interest of federal health agencies.

These authors of the IDSA guidelines are empowered by the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC).

The former NIH Lyme disease program manager was Phillip J. Baker. Allocations for Lyme disease were extremely biased. Most of the NIH funding went to certain authors of the Lyme guidelines, their associates, and their institutions. Some of the research funded appears to have been contrived to reach desired outcomes. Some of these studies have been heavily criticized. As a reward for his allegiance, Dr. Baker was made the president of the American Lyme Disease Foundation (ALDF) when he retired. Some guideline authors are "scientific advisors" to the ALDF. The ALDF is known by advocates as an HMO friendly, anti Lyme patient organization.

Willy Burgdorfer, formerly with the NIH and for whom the Lyme bacterium was named, made the observation that after 30 years (of research by the Lyme cartel) we still know little or nothing. Dr. Burgdorfer, who is likely the world's most expert authority in the characteristics of the Lyme bacterium, believes that late-stage cases of Lyme disease require long-term antibiotics; contrary to the recommendations of the IDSA guidelines.

The CDC has endorsed the IDSA Lyme guidelines on their public information page. The CDC has many employees who are also members of IDSA, a private organization. In addition, some of the authors were former CDC employees and have close ties to the CDC. One question is whether the CDC should be officially endorsing these guidelines, especially given their controversy. The CDC itself has massive conflicts of interest with regard to Lyme disease. Much of this was made possible by the passage of the Bayh-Dole Act in 1980. This allowed intellectual property rights to be held by those performing research funded by the federal government. As a result, the CDC and certain of its employees involved in Lyme disease have patent interests in vaccines and Lyme disease testing methods. The CDC also assigned rights to a Lyme vaccine to SmithKline Beecham Corporation. Approval by the CDC virtually insures a large market for a vaccine.

The content of the CDC's Lyme disease information has been diluted to the point that it is of little benefit to the public and medical practitioners. During vaccine development, the definition of Lyme disease was altered to one more "vaccine friendly." The purpose was to limit the disease definition so as to maximize the apparent efficacy of the vaccine in FDA trials.

In the end, the SmithKline Beecham vaccine turned out to have serious adverse effects, including death, and was withdrawn from the market. Evidence suggests the CDC knew of these side effects before the vaccine was approved. A logical conclusion is that the CDC and its employees are more concerned about protecting their financial health than the public's health.

The IDSA/CDC's misinformation and attempts to eliminate ILADS guidelines.

The CDC has standards for Lyme disease testing for surveillance purposes that are highly restrictive and that very few, even with proven Lyme disease, can meet. The result is that Lyme disease is vastly underreported, even in areas where it is recognized and where physicians are more aware. The serologic tests are touted to be highly accurate when, in fact, they are not,

particularly when performed by large high volume laboratories. The CDC does caution that the strict testing criteria for surveillance purposes should not be used for diagnosis. But they are. The IDSA guidelines promote the use of the restrictive CDC testing criteria for diagnostic purposes.

While the IDSA guidelines are endorsed by the CDC and touted on the CDC's Lyme disease information web page, the alternative ILADS Lyme guidelines are given no mention.

In a closed meeting involving high level CDC employees and the president of IDSA at the time, Walter Stamm, a directive was approved to eliminate "rogue" Lyme disease guidelines. Although names were not mentioned in the released minutes of this meeting, this could have only referred to the alternative patient friendly guidelines issued by ILADS.

Enforcement methods for adherence to IDSA guidelines.

Harassment of competent and credible Lyme disease specialists who treat in accordance with ILADS guidelines is not uncommon. Investigations are usually conducted by medical boards that rely on IDSA guidelines and use IDSA "Lyme disease experts" as witnesses. There are a number of examples of this. In many states, the environment for Lyme specialists is so toxic; patients must travel to other states for diagnosis and treatment. Some states, such as California, have adopted legislation to protect legitimate Lyme physicians from harassment.

In essence, the enormous power of IDSA combined with endorsement by the CDC was used to drive "competitors" out of business and left patients whose insurers relied on the IDSA Lyme guidelines with no treatment options. This abuse of monopoly powers is one of the factors that led to the antitrust investigation of IDSA and question the process used to develop its Lyme guidelines. It was during this investigation that numerous and significant conflicts of interest by the panel were discovered.

Treatment guidelines, even corrupted ones, are a tool for controlling medicine through the centralization of medical decision making. Practice guidelines are central to the profitability of HMO's and health insurers.

Dr. David Eddy, senior advisor to Kaiser Permanente, stated that "if the fight to control health care costs is to be successful, it will have to address [the decisions physicians make about treatments.]" (Eddy DM. Three Battles to Watch in the 1990's. JAMA. 1993; 270(4): 520-26). Dr. Eddy went on to say "[i]t would not be stretching things too far to say that whoever controls practice policies controls medicine." (Eddy DM. Clinical Decision Making: From Theory to Practice, Practice Policies—What Are They? JAMA. 2000; 263(6): 877–878.).

From an altruistic point of view, ethically and competently derived guidelines could benefit patients as well as control costs. But when guidelines are driven by interests that are not aligned with the public interest, as they are when they are exclusionary of divergent opinion and permit conflicts of interests, they become tools of the pharmaceutical and insurance industries. Thus, the observations made by Dr. Eddy can have very negative consequences.

The Connecticut Attorney General's IDSA Lyme guideline antitrust investigation

The Connecticut Attorney General concluded its investigation finding that the IDSA Lyme panel had substantial conflicts of interest, excluded divergent opinion, and suppressed scientific evidence. This panel created guidelines that took on the force of law and were treated as mandatory by insurers, medical boards and courts of law. Laws are generally adopted through

open public debate with input from all affected stakeholders. But the IDSA guidelines panel did not include community physicians, physicians from the International Lyme and Associated Diseases Society, and Lyme patients (http://www.ct.gov/ag/cwp/view.asp?a=2795&q=414284).

The Connecticut Attorney General forced the IDSA to put together a new panel free from conflicts of interest to review the guidelines adopted in 2006, permit opposing scientific evidence to be submitted and considered by the panel, and to have a public hearing with presentations that will air live over the Internet. Notwithstanding this settlement, it is apparent that the IDSA is intent on protecting its professional turf at the expense of patient health care. It has made this clear by stacking the panel with IDSA members and research academics and excluding all community physicians and members of ILADS. One panel member has been successfully removed from the panel and another is under scrutiny—both because they had drafted previous guidelines in contravention of the settlement agreement with the Attorney General. Inclusion of divergent viewpoints is necessary for treatment guidelines to include options for patients.

The review is still in process.

An independent commentary on the applicability of antitrust law in the development of clinical practice guidelines is found at http://lyme.kaiserpapers.org/pdfs/lymeantitrust.pdf

My experience

I was a victim of the IDSA/CDC guidelines.

My saga with Lyme disease started on a 1994 road trip to Oregon and California with my dog, Bo, We were both infected, most likely at a highway rest area. After we returned home, we both had the distinctive expanding circular rash considered the "hallmark" sign of Lyme disease. Mine was on my chest and reached about a foot in diameter. I did not know about Lyme disease at the time and did not realize the significance of the rash. The rash eventually faded and I forgot about it.

During next the six years I was infected but did not know it, I saw four primary care doctors, two ophthalmologists, one allergist, and two cardiologists. I saw each of these doctors multiple times in connection with my Lyme symptoms. This does not include the numerous times I went to ER during which my resting heart rate was recorded at over 250 beats per minute. An MRI of my brain showed lesions consistent with neurological Lyme. In a span of about 18 months, I had 11 cardiac catheter procedures to determine the cause and try to correct my cardiac irregularities.

When it was clear that Kaiser could not help, it took me about an hour on the Internet to research my symptoms and learn the significance of the rash I had. The findings indicated Lyme disease.

Eventually, I saw an infectious diseases doctor at Kaiser. He ordered the cheap and unreliable ELISA Lyme "screening" test according to the IDSA guidelines. The sample was sent from Oregon to a contracted lab on the East Coast. The interval between blood draw and analysis was more than two weeks, which may have rendered the sample worthless because of degradation. (I later learned that Kaiser has been known to send East Coast samples to labs in the West.) Strain variations between the East Coast and West Coast can also be a factor in test outcomes.

The result of my test was, of course, negative. The infectious diseases doctor dismissed my rash. He wrote a two-page report justifying his denial. This was not a casual dictation. It took about three months for the report to appear in my medical record. In it, he even fabricated information.

One entry read that I believed in Lyme "conspiracists," something I never said and never brought up. This was intended to question my mental state.

Later, a Kaiser neurologist tried to help me. He ordered the ELISA and Western Blot tests through Kaiser and a Western Blot test by an independent lab specializing in tick-borne diseases. I had to pay for the independent lab test. I did not trust the lab Kaiser used.

He was denied his order to have the Western Blot tests done since the IDSA/CDC/Kaiser protocol called for a positive ELISA before the more expensive Western Blot tests could be done. Kaiser again shipped the sample to the East Coast and again my ELISA was negative.

The Western Blot test that was done at the specialty lab came back highly positive with specific indicators for Lyme. The neurologist wrote another infectious disease doctor that these test results were not consistent with Kaiser's negative ELISA test. The infectious diseases doctor replied that the ELISA is highly accurate (a false IDSA/CDC claim) and I could not possibly have Lyme disease. In a letter to the chief of infectious diseases, I asked about the significance of the rash I had. He wrote back while I may have had Lyme disease, I no longer had it. In his opinion, it cured itself (although I had ongoing symptoms). The positive Western Blot was not in my record.

Finally, I was able to change health plans and see a Lyme specialist in San Francisco. There were no doctors competent in Lyme disease in my region. My life-threatening heart arrhythmias resolved within a month of antibiotic treatment (although not all cardiac symptoms resolved). It took about four years of antibiotic treatment to become functional again.

There was so much damage to my heart that most cardiologists recommended a heart transplant. This was not an option for me because of the immune suppressing drugs required. Ultimately, a complicated and expensive open heart surgery was done at Stanford University.

The costs associated with my Lyme disease were in the many hundreds of thousands of dollars. Medicare paid for the open heart surgery. The cost of the loss of 10 years of my life, during which time I was unable to work, is incalculable. My companion, Bo, had to be euthanized.

Conclusion and recommendations.

The end result of the IDSA/CDC misinformation about Lyme disease is that most doctors are incredibly ignorant about Lyme disease believing it is rare or nonexistent in their areas and that the disease is "hard to catch and easy to cure". Even using figures that greatly understate the frequency of the disease, Lyme far outnumbers AIDS in terms of disease frequency. Most doctors do not question the information provided by the CDC.

The CDC information has never been subjected to peer review as required under the Office of Management and Budget (OMB) Final Information Quality Bulletin for Peer Review (OMB Bulletin). Patient advocacy groups have requested a peer review by the CDC and have been denied. This review should be ordered through a government mandate.

The NIH has conducted studies that are being relied upon to deny patients treatment—yet the data underlying these studies has not been made available for analysis by others although these studies have been sharply criticized. A study funded by the NIH that used non-human primates and was finished more than 6 years ago has never been published. This publicly funded project may yield vital information on Lyme disease and persistence. This data has not been released and should be released.

It is difficult to get funding for Lyme disease from non-government sources because there is no real money in treating the disease, which relies on generic antibiotics. However, Lyme disease can be a goldmine for pharmaceutical companies that have medications to treat and mask multiple ongoing symptoms rather than curing the disease itself. In the long run, this approach can cost far more and the patient does not achieve wellness.

The simple truth is that some government health agencies have operated in a corrupt fashion, furthering the interests of a handful of researchers, suppressing scientific evidence and abandoning patients as not even being "on the agenda". Lyme patients and their physicians currently have no voice in Lyme disease funding or health care policy matters.

The federal government must step in to correct these injustices. State governments are limited in what they can do, particularly with regard to federal health agencies. And all or most state departments of health are dominated by CDC/IDSA information. Inappropriate relationships between government health agencies and private medical societies, pharmaceutical companies, and HMO's should be scrutinized.

For additional information on Lyme disease and some of the corruption involved, I highly recommend "Cure Unknown: Inside the Lyme Disease Epidemic" by Pamela Weintraub and the award winning film documentary about Lyme disease, "Under Our Skin." Also, Lorraine Johnson, JD, MBA, maintains a blog that discusses the medical-legal-ethical issues surrounding Lyme disease, that include treatment guidelines, the Connecticut antitrust action against the IDSA, and the interplay of universal health care at **http://tinyurl.com/lymepolicywonk.**

A health care reform plan should give careful consideration to the dangers of inappropriately sponsored and developed clinical practice guidelines and their application in health care reform issues. The potential misapplication of medical guidelines can result in much greater costs to government. These include increased disability and government subsidies resulting from patient abandonment, loss of national productivity due to increased numbers of sick people unable to work, and the greater costs of long term symptomatic treatment and potentially expensive medical procedures rather than the treatment of the disease itself.

Elimination of medical corruption is essential to the success of any health care reform plan.

Thank you very much for the opportunity to write this letter.

Sincerely,

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